CHAPTER 2

ASSESSMENT PRINCIPLES AND PRACTICES

This Chapter provides guidance on the principles and practices involved in conducting on-site assessments. It discusses the purpose of NELAC on-site assessments. It also provides an overview of general assessment principles and discusses assessment tools and techniques, such as how to establish objective evidence of compliance or non-compliance and how to design and conduct effective staff interviews. The role of the assessor and interpretation of assessment results is also discussed.

2.1 Purpose of On-Site Assessments

The purpose of the on-site assessment is to determine whether the laboratory is meeting all of the applicable NELAC standards for performance by observing laboratory practices and collecting objective evidence. During the on-site assessment the assessor verifies that the laboratory's quality assurance program is adequate, effective, and is being implemented reliably and consistently. Where this is not the case, the on-site assessment team must document deficiencies by collecting objective evidence[1] . At the completion of the assessment, the assessors must identify all deficiencies found during the assessment. These findings are formalized in a written report which is used together with the laboratory's application materials and the results of NELAC proficiency tests to grant, deny or revoke accreditation.

On-site assessments may play several different roles in the overall laboratory accreditation process, depending on the laboratory's status and the reason for conducting the assessment. For example:

- If the assessment is the initial site visit conducted in response to an application for accreditation, it serves as an initial, comprehensive assessment of the laboratory and its quality system. All areas of the laboratory should be given the same level of examination.

- If the assessment is conducted as part of a routine re-assessment to support renewal of laboratory accreditation, it reaffirms that the laboratory is continuing to comply with all applicable requirements. However, if deficiencies have been noted in the past, the assessor can use the site visit to pay special attention to verifying that past corrective actions are continuing to work effectively and that previous deficiencies have not recurred.

- If the assessment is conducted to verify the efficacy of corrective actions implemented in response to deficiencies that were recognized during a previous assessment or as a result of unsuccessful performance on a proficiency test, the scope of the assessment may be restricted to verifying the efficacy of specific corrective actions.

- If the assessment is conducted as an unannounced visit, it may be intended to investigate a complaint or to evaluate specific areas where deficiencies may exist or have occurred in the past. It may be a comprehensive assessment, depending on the priorities and policies of the

[1] Objective evidence: Qualitative or quantitative information, records, or statements of fact pertaining to the quality of an item or service or to the existence and implementation of a quality system element, which is based on observation, measurement, or test and which can be verified. (ANSI/ASQC Q1011-1-1994)

accrediting authority.

In all cases, the general procedures provided in this manual and the NELAC standards should serve as the basic criteria against which the laboratory is evaluated. Assessors should recognize that compliance with state supplemental standards may also need to be evaluated during the on-site assessment. This manual provides procedures for evaluating laboratories against the NELAC standards and does not address state supplemental standards.

2.2 Assessment Principles

The on-site assessment should be an independent examination, made by a professional expert and based on established standards. As a result of an on-site assessment, the assessor expresses an independent, professional opinion concerning the extent to which the laboratory QA system and practices meets or does not meet the established standards. Assessments have the following general characteristics:

- ➢ They should be performed by a person or persons who have no business connections, interests, or affiliations that might influence their assessment capabilities.
- ➢ They should be adequately planned and staffed; and assessment staff should be adequately supervised.
- ➢ They should be performed by a person or persons who have adequate technical training and experience as assessors.
- ➢ They should be conducted with an attitude of objective independence in all matters relating to the assessment.
- ➢ Assessors should exercise due professional care in performing the assessment and preparing the final report.
- ➢ All assessment findings and conclusions should be based on detailed study and evaluation of available information.
- ➢ All findings made during the assessment should be based on sufficient objective evidence obtained through assessment, observation, inquiries, and confirmation.

The NELAP on-site assessment is an evaluation of a laboratory's facility, equipment, personnel, and quality system. It is designed to document conformance or non-conformance with all applicable NELAC requirements.

The American National Standards Institute (ANSI) defines the assessment process as:

> *A systematic and independent examination to determine whether quality activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.*[2]

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2 See: Guidelines for Auditing Quality Systems - Auditing, ANSI/ASQC Q10011-1-94.

With this general definition in mind, NELAP on-site assessment teams should design and conduct their assessments to answer the following basic questions:

1. Does the laboratory facility, equipment, and personnel meet all applicable NELAC requirements?

2. Does the laboratory's quality assurance program meet all of the applicable NELAC requirements?

3. Do interviews confirm that laboratory managers and staff are familiar with and understand the requirements of the laboratory's quality assurance program?

4. Do observations confirm that all aspects of the laboratory quality assurance program practiced regularly by laboratory managers and staff?

5. Do laboratory written records verify that all aspects of the quality assurance program have been practiced regularly by all managers and staff?

6. Do the laboratory's proficiency testing records demonstrate that its quality assurance practices conform with all applicable NELAC requirements?

The on-site assessment should be designed as a systematic approach to answering each of these questions for the general NELAC quality system standards and for method-specific requirements. If the on-site assessment team determines that the answer to any of these questions is negative, all deficiencies must be thoroughly documented, through observation and by collecting objective evidence. Each deficiency noted and its supporting evidence must be presented in the final report.

2.3 Assessment Tools and Techniques

Each activity conducted during the fact-finding phase of an on-site assessment falls into one of five categories: assessment,, observation, inquiry, confirmation, and recording. This section presents a brief discussion of some important tools that should be used to support activities in these categories.

2.3.1 Assessment and Observation

The fact-finding phase of every assessment should begin with a full laboratory tour. All members of the on-site assessment team should attend the same tour, led by one or two knowledgeable laboratory representatives. The purpose of this initial tour is to familiarize the on-site assessment team with the laboratory, allow the team to verify the general lay-out of the laboratory, and identify any discrepancies between the general facility information submitted with the application for accreditation and the actual facility. Team members should make note of any aspects of the laboratory that are different than expected. In general, any significant observations made during the laboratory tour should be noted for further investigated later, rather than on the spot. This will allow the tour to be conducted quickly. The tour should involve a walk-through of the entire facility, including:

- ➢ Laboratory office space

- ➢ Sample receipt and storage area(s)
- ➢ Laboratory supply storage areas
- ➢ Facility support equipment and systems (e.g., primary and back-up power supplies, HVAC systems, laboratory water systems, etc.)
- ➢ Analytical balance areas
- ➢ Sample and standards preparation areas
- ➢ Analytical areas
- ➢ Data handling and records management/storage areas

Following the general tour, individual members of the assessment team should make a thorough assessment of the areas to which they are assigned. During this more detailed tour and assessment, the following types of observations should be made and recorded:

- ➢ Identification and assessment of laboratory instruments;
- ➢ Assessment of instrument maintenance and calibration logs;
- ➢ Assessment of standards and reagent labels and logs;
- ➢ Observation of staff conduct;
- ➢ Assessment of analytical bench space;
- ➢ Assessment of glassware and supply storage cabinets;
- ➢ Assessment of analysts' log books or data recording sheets.

During this detailed assessment, the assessor should request that a knowledgeable laboratory representative (e.g., manager or lead analyst) describe all of the principal procedures used in the area. The assessor should note any observations that require further investigation and follow up later to gather additional information through interviews or records reviews.

2.3.2 Staff Interviews

During the detailed assessment of laboratory work areas, assessors should begin asking questions of the staff. In general, questions should be probing and not leading, and assessors should avoid asking questions with simple yes/no answers. Encourage staff to elaborate by being attentive, patient and interested. All of the principles that apply when conducting staff interviews should be utilized when speaking informally in the laboratory.

Formal staff interviews should be planned and scheduled in advance, if possible. The lead assessor should ensure that adequate and appropriate office space, if needed, will be made available for conducting private interviews. Assessors should employ good interviewing techniques and should be prepared to ask probing questions and to rephrase questions if necessary to receive a satisfactory answer. Assessors should maintain neutral body language so as not to provide visual cues that lead the respondent toward certain answers. Throughout the interview, assessors should make note of follow-up and other questions to ensure that they are not forgotten.

The following methods should be utilized in conducting interviews:

Planning the Interview

- ➢ Arrange all logistics such as time, duration, and location.
- ➢ Define the purpose for each interview.
- ➢ Organize your thoughts and establish a general sequence for questioning.
- ➢ Practice on a colleague if necessary.

Interview Setting

- ➢ Attempt to ensure that the respondent feels that there is sufficient privacy.
- ➢ When appropriate, conduct discussions in the respondent's work area.
- ➢ Interviews should be "one-on-one", whenever possible.
- ➢ Minimize potential distractions.

Conducting the Interview

Establish Rapport - Ask simple questions or verify information that has been given already (educational background, years in present position comments concerning respondents interest/hobbies, if known) before moving into the more pertinent interview material.

- ➢ Request a brief overview of the respondent's responsibilities in the laboratory.
- ➢ Ask open-ended questions (i.e., "how" or "what" questions) rather than obvious yes/no questions (i.e., "do you..." questions).
- ➢ Ask follow-up questions where answers are unclear or incomplete. Remember, you may need to ask the same question several different ways to get the information needed.
- ➢ Avoid making assumptions.

- ➢ Avoid leading questions or body language.
- ➢ Provide feedback to the respondent as appropriate, to encourage complete answers.
- ➢ Tolerate silences in order to allow the respondent to formulate thoughts and responses.
- ➢ Do not expect any one person to have complete knowledge. Talk to others.
- ➢ Do not get sidetracked in areas outside the scope of the assessment, such as regulatory policy or the relative effectiveness of methods.
- ➢ Be aware of the chronic complainer or lobbyist. These individuals may attempt to use assessors to advance their complaints to management.
- ➢ Avoid jumping to conclusions during an interview. Get all the facts, including views from other people, before concluding that a deficiency exists.
- ➢ Remain calm and professional. Avoid becoming involved in internal laboratory issues which have no bearing on the assessment.
- ➢ Verify information obtained during staff interview with observations and discussions with fellow assessment team members. Seek objective evidence and make an independent professional judgement .

Interpersonal Considerations

- ➢ Shake hands.
- ➢ Maintain appropriate eye contact.
- ➢ Maintain appropriate distance.
- ➢ Use appropriate voice tone and inflection.
- ➢ Make sure the respondent has finished speaking with each response. Do not complete the respondent's sentences.

Closing the Interview

- ➢ Try not to monopolize one individuals's time. Remember that the employee has other work to do.
- ➢ End on a positive note.

- ➢ Summarize your understanding of key points to ensure accuracy.

Documenting the Interview

- ➢ Record the context of the interview (time, date, name and position of respondent).
- ➢ Make notes of key points during the interview; do not attempt to record a verbatim transcript. Whenever possible, read your notes aloud to put the respondent at ease.
- ➢ Take a few minutes to summarize the outcome of the interview before beginning the next interview.

2.3.3 Confirmation

Throughout the assessment, observation, and inquiry procedures, assessors should compile indications of possible deficiencies in laboratory performance. Each must be investigated to the maximum extent possible. Every deficiency found must be supported by objective evidence.

Written records such as log books, data sheets, chain-of-custody records, personnel or other files, or data packages are excellent sources of objective evidence. Sample labels, sign-in/sign-out sheets, and other materials kept in the laboratory or in storage areas are also sources of objective evidence. Often, evidence arises when raw data and reports are compared and discrepancies found. Objective evidence may be statements of fact made by laboratory personnel. Assessors should be careful to ensure that a statement made by one individual can be independently corroborated by at least one or more additional staff members. Assessors should always attempt to find written qualitative or quantitative evidence, however, even where numerous staff have consistently noted the same deficiency. Such evidence is useful first because it provides clear and unbiased documentation of the deficiency and second, because the nature of the evidence may be an indication of the type of corrective action that will be most effective.

While objective evidence should be collected as it is encountered throughout the assessment, it is important that the assessment team allow time near the end of the assessment dedicated to seeking out objective evidence. Team work will make the search for qualitative and quantitative evidence efficient and effective. The assessment team should meet (in a private setting) to discuss all apparent deficiencies and develop (1) a plan for seeking the objective evidence and (2) a list of records or documents to be requested. The lead assessor should also evaluate the relative importance of each point to be investigated and the amount of work involved in finding the evidence. Team manpower should be applied effectively to ensure that the most important evidence is found as quickly as possible.

2.3.4 Recording

All activities conducted by the assessment team while on-site must be thoroughly documented in notes or checklists. Notes should be dated, the context noted (i.e., name of staff/manager, laboratory work area, time of day, etc.), and all entries should be made in ink. The results of all interviews should be recorded, including the assessor's written summary following each interview.

Assessors should record results on NELAP on-site assessment checklists, which appear in Appendix A. Checklists serve many purposes.

- ➢ They ensure completeness of the assessment, since they provide a comprehensive list of the criteria against which the laboratory must be evaluated.
- ➢ They facilitate the uniformity of on-site assessments.
- ➢ They provide support for the significance of individual criteria to laboratory personnel because checklist items are directly linked to specific NELAC standards.

At the completion of an assessment, the assessment team should have a comprehensive record of activities. All identified deficiencies should be traceable to specific entries in the record, noting both observations (i.e., statements made by laboratory staff) and objective evidence gathered to support the finding of a deficiency. All deficiencies will be discussed with management during the closing conference (Section 4.0) unless a criminal investigation appears likely.

2.4 Role of the Assessor and Interpreting Assessment Results

The assessor is a fact-finder, not a decision-maker with respect to granting accreditation. His/her role is to observe and note the extent to which the laboratory meets applicable standards. Near the end of an on-site assessment, the lead assessor should meet with the team to identify all of the deficiencies found and review the observations and objective evidence supporting each. Together, team members should determine whether the evidence gathered constitutes the apparent deficiency.

Assessors should strive to maintain an informed, professional, and objective demeanor at all times. ANSI makes the following statement concerning important attributes for assessors:

> *Auditor [Assessor] candidates should be open minded and mature, possess sound judgement, analytical skills, and tenacity; have the ability to perceive situations in a realistic way, to understand complex operations from a broad perspective, and to understand the role of individual units within the overall organization.*

ANSI further identifies a list of responsibilities that assessors should fulfill, including:

- ➢ Obtaining and assessing evidence fairly;
- ➢ Remaining true to the purpose of the assessment without fear or favor;
- ➢ Constantly evaluating the effects of observations and personal interactions during an assessment;
- ➢ Treating concerned personnel in a way that will best achieve the assessment purpose;
- ➢ Performing the assessment without being distracted;

- ➢ Committing full attention and support to the assessment process;
- ➢ Reacting effectively in stressful situations;
- ➢ Arriving at conclusions that are supported by observations and evidence; and
- ➢ Remaining true to a conclusion despite pressure to change that is not based on evidence.[3]

Throughout the assessment, the assessors' chief priority is to preserve the integrity of the assessment by maintaining objectivity and ensuring complete and reliable documentation.

Section 2.5 Potential Violations

Sometimes, when conducting on-site assessments, assessors may uncover possible evidence of regulatory compliance violations, data falsification, or criminal activity. At such time, the on-site assessment may expand from an assessment to a preliminary investigation, especially when assessors are also employees of accrediting authorities with enforcement responsibilities. However, the assessors should proceed with the laboratory evaluation in order to produce a final report with respect to laboratory accreditation in the event that no violations are proven. Because the statutes associated with criminal investigations may vary from state-to-state, it will be imperative that each accrediting authority train their assessors accordingly.

If possible, enough objective evidence should be acquired to enable the accrediting authority to determine if further enforcement action or investigation is warranted. Assessors who are unfamiliar or uncomfortable with this role should contact the accrediting authority for additional instructions. In any event, the assessment team should notify the accrediting authority of their suspicions as soon as possible, but not later than two working days after the assessment.

See *Guidelines for Auditing Quality Systems - Auditing,* ANSI/ASQC Q10011-1-1994.